EXHIBIT A

A088 Subpoena in a Civil Case

Issued by the

United States District Court

District of New Jersey

IN RE: '318 PATENT INFRINGEMENT LITIGATION

SUBPOENA IN A CIVIL CASE

TO: Ranbaxy, Inc.
c/o Corporation Service Company
830 Bear Tavern Rd.
West Trenton, NJ 08628

Case Number:[1] C.A. No. 05-356-KAJ (consolidated)
(District of Delaware)

☐ YOU ARE COMMANDED to appear in the Unites States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. Please See Schedule A Attached

PLACE OF DEPOSITION:	DATE AND TIME
Esquire Deposition Services, 90 Woodbridge Center Dr. #340 Woodbridge, NJ 07095 Recording Method: By stenographer and videotape	JUNE 20, 2006 AT 10:00 A.M.

☐ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects): Please See Schedule B Attached

PLACE	DATE AND TIME

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE AND TIME
Attorney for Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc.	June 2, 2006
ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER James G. McMillan, III, Esquire Bouchard, Margules & Friedlander, P.A. 222 Delaware Avenue, Suite 1400, Wilmington, DE 19801 Tel: 302-573-3500	James G. McMillan, III

(See Rule 45, Federal Rules of Civil Procedure, Parts C&D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

DATE PLACE

SERVED

SERVED ON (PRINT NAME) MANNER OF SERVICE

SERVED BY (PRINT NAME) TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C&D

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(2)(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden

(3)(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

1. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

2. As used herein, "ANDA" shall mean Abbreviated New Drug Application Number 77-588.

3. As used herein, "Plaintiffs" refers to Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc., either individually or collectively.

4. As used herein, "You," "Your," or "Yours," shall mean Ranbaxy, Inc, Ranbaxy, Inc.'s corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents, employees and any individuals or entities that at any time have acted or purported to act on behalf of Ranbaxy, Inc. or its successors.

TOPICS

1. The notice You sent to Plaintiffs on May 6, 2005, attached hereto as Exhibit 1.

2. Your patent certification regarding the '318 patent in connection with ANDA No. 77-588.

EXHIBIT 1

RANBAXY

RANBAXY INC., 600 COLLEGE ROAD EAST, PRINCETON, NJ 08540. PHONE: (609) 720-9200 FAX: (609) 720-1155

May 6, 2005

VIA FACSIMILE (609) 730-2323

CONFIRMATION VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chief Executive Officer
Janssen Pharmaceutica, Inc.
1125 Trenton-Harbourton Road
PO Box 200
Titusville, New Jersey 08560-200

Re: Galantamine Hydrobromide Tablets (4 mg, 8 mg, 12 mg)
ANDA No. 77-588
U.S. Patent Nos. 6,099,863 and 6,358,527

Dear Madam or Sir:

Pursuant to Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act ("FDCA") and 21 C.F.R. § 314.95, you are hereby notified as follows:

(1) Ranbaxy Laboratories Limited ("RLL") has submitted and the FDA has received an abbreviated new drug application ("ANDA") under FDCA Section 505(j)(2)(B)(ii) which contains bioavailability or bioequivalence data in order to obtain approval to engage in the commercial manufacture, use or sale of drug products containing **galantamine hydrobromide.**

(2) RLL's ANDA referred to in paragraph (1) has been assigned No. **77-588**.

(3) The established name for the drug product is **galantamine hydrobromide**, and the proprietary name of the drug product as listed in the electronic edition of FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") is **Reminyl®.**

(4) RLL's proposed drug product is in the form of tablets that contain 4 mg, 8 mg, and 12 mg of galantamine hydrobromide as the active ingredient. U.S. Patent Nos. 4,663,318; 6,099,863; and 6,358,527 are listed in the Electronic Orange Book with respect to this drug product. U.S. Patent No. 4,663,318 is listed as

having an expiry of December 14, 2008 and U.S. Patent Nos. 6,099,863 and 6,358,527 are listed as having an expiry date of June 6, 2017.

(5) RLL's ANDA No. 77-588 certifies under FDCA Section 505(j)(2)(A)(vii), paragraph III, that U.S. Patent No. 4,663,318 will expire on December 14, 2008.

(6) RLL's ANDA No. 77-588 certifies under FDCA Section 505(j)(2)(A)(vii), paragraph IV, that in the opinion of RLL and to the best of its knowledge, no valid claim of U.S. Patent Nos. 6,099,863 and 6,358,527 will be infringed by the manufacture, use, sale, or offer to sell of the drug products for which ANDA No. 77-588 has been submitted. A detailed statement of the factual and legal basis for this opinion follows.

U.S. Patent No. 6,099,863 is Not Infringed

U.S. Patent No. 6,099,863 ("the '863 Patent"), entitled "Fast-dissolving galantamine hydrobromide tablet," issued on August 8, 2000. This patent contains 10 claims, of which claims 1 and 10[1] are independent claims. The claims are as follows:

1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

2. A tablet according to claim 1 wherein the disintegrant is crospolyvidone or croscarmellose.

3. A tablet according to claim 1 wherein the carrier further comprises a glidant and a lubricant.

4. A tablet according to claim 3 wherein the glidant is colloidal anhydrous silica and wherein the lubricant is magnesium stearate.

5. A tablet according to claim 1 comprising by weight based on the total weight:
(a) from 2 to 10% galanthamine hydrobromide (1:1);

[1] Pursuant to 21 CFR §314.94(a)(12)(iv), an ANDA applicant is not required to certify to process claims. Nonetheless, our noninfringement position is provided to ensure that Janssen has an opportunity to review RLL's noninfringement position with respect to this process claim.

(b) from 83 to 93% spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25);
(c) from 0.1 to 0.4% glidant;
(d) from 3 to 8% insoluble crosslinked polymeric disintegrant; and
(e) from 0.2 to 1% lubricant.

6. A tablet according to claim 5 comprising
(a) about 2 to 10% galanthamine hydrobromide (1:1);
(b) about 83 to 93% spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25);
(c) about 0.2% colloidal anhydrous silica;
(d) about 5% crospolyvidone; and
(e) about 0.5% magnesium stearate.

7. A tablet according to claim 1 which is film-coated.

8. A tablet according to claim 7 wherein the film-coat comprises a film-forming polymer and a plasticizer.

9. A tablet according to claim 8 wherein the film-coat weighs from about 3% to about 8% of the uncoated tablet core.

10. A process of preparing a tablet according to claim 3 comprising the steps of:
(i) dry blending the active ingredient, the disintegrant and the optional glidant with the diluent;
(ii) optionally mixing the lubricant with the mixture obtained in step (i);
(iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and
(iv) optionally film-coating the tablet obtained in step (iii).

Claim 1 is directed to a tablet that includes as an active ingredient a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier. The carrier includes a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Ranbaxy's galantamine hydrobromide tablet does not literally infringe claim 1 because Ranbaxy's tablets do not include an insoluble or poorly soluble cross-linked polymer disintegrant. Ranbaxy's tablets include galantamine hydrobromide, MicroceLac® 100, colloidal

silicon dioxide, magnesium stearate, and pregelatinized starch. The tablets formed with these ingredients are coated with Opadry coatings.

Microcelac® 100 is a spray-dried mixture containing 75% alpha-lactose monohydrate and 25% microcrystalline cellulose. Neither alpha-lactose monohydrate nor microcrystalline cellulose can be characterized as being an insoluble or poorly soluble cross-linked polymer disintegrant. Lactose is a diluent which is a disaccharide. There is no cross-linking in this polymer, it functions as a diluent or filler, and is water soluble. As listed in the Handbook of Pharmaceutical Excipients, Fourth Edition, lactose is soluble at 1 in 4.63 at 20°C, 1 in 3.14 at 40°C, 1 in 2.04 at 50°C, 1 in 1.68 at 60°C, and 1 in 1.07 at 80°C.

Microcrystalline cellulose is a carbohydrate having multiple repeating units of cellulose and is used in Ranbaxy's tablet as a diluent. It is not a cross-linked polymer but instead is a long chain polymer that does not have cross-linking.

Colloidal silicon dioxide is neither a polymer nor cross-linked and is used by Ranbaxy as a glidant in the tablets, not as a disintegrant. Magnesium stearate is long chain polymer that is not cross-linked. It also is well-known as being a lubricant. For example, the '863 patent describes magnesium stearate as being a lubricant. See Col. 3, line 39.

Starch is a polymer formed from glucose subunits. According to the Handbook of Pharmaceutical Excipients, Fourth Edition, starch does not compress well and tends to increase tablet friability and capping if used in high concentrations. Pregelatinized starch is a modified form of starch in which the granules have been chemically or mechanically processed to rupture the starch granules to render the starch flowable and directly compressible. Neither starch nor pregelatinized starch is cross-linked.

Ranbaxy's tablets also do not infringe claim 1 under the doctrine of equivalents. For example, the '863 patent describes the requirements for the disintegrant in a manner that excludes pregelatinized starch. In Col. 3, lines 28-32, the patent states that the dissolution specification for the tablets was not met unless "an insoluble or poorly soluble cross-linked polymer such as, for example, crospolyvidone or croscarmellose was employed." Again, pregelatinized starch is not a cross-linked polymer.

Moreover, during prosecution, the applicants amended claim 1 to include the limitation that the disintegrant be an insoluble or poorly soluble cross-linked polymer. The claims were initially rejected by the Examiner under 35 USC § 112 for lack of enablement. The Examiner stated that the disintegrants crospolyvidone or croscarmellose are critical or essential to the practice of the invention and because they are not included, the claims are not enabled. The Examiner pointed to the text of the application that shows ingredients including crospolyvidone or croscarmellose are essential to meet the necessary dissolution requirement.

In response to this rejection, the applicants amended claim 1 to include the limitation of the disintegrant being "an insoluble or poorly soluble cross-linked polymer" and in the Remarks argued:

> Claim 1 has been amended to more particularly point out and distinctly claim that which applicants regard as the invention. More specifically, Claim 1 has been amended to require that the disintegrant be an insoluble or poorly soluble cross-linked polymer disintegrant. [. . .] By the above amendment, Applicants have amended Claim 1 to require that the disintegrant is 'an insoluble or poorly soluble cross-linked polymer disintegrant' which provides the required dissolution specification of 80% after 30 minutes.

See Amendment dated January 18, 2000, page 2. The applicants pointed to the application as providing support for the amendment to claim 1.

Based on this amendment and argument, the Examiner allowed the claims. In the Examiner's statement of reasons for allowance, the Examiner stated that the claims were allowed because "The particular carrier combination of a spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent and an insoluble or poorly soluble cross-linked polymer disintegrant enables the fast dissolution of said tablet. Disintegrants having a large coefficient of expansion, such as crospolyvidone or croscarmellose enables a dissolution specification of at least 80% after 30 minutes, which is not recognized in the prior art." See Notice of Allowability dated March 11, 2000, page 2.

Under the doctrine of equivalents, the patentee cannot now expand the scope of the claims to include that which was disavowed either in the application or during prosecution to obtain allowance of the claims, namely, a disintegrant that is not cross-linked, such as

pregelatinized starch. Accordingly, claim 1 and dependent claims 2-9 are not infringed by Ranbaxy's galantamine hydrobromide tablet either literally or under the doctrine of equivalents.

Independent claim 10 recites a process for making the tablet of claim 3, which depends from claim 1. Claim 3 limits claim 1 by further reciting a glidant and a lubricant. Because claim 3 depends from claim 1 it requires the presence of an insoluble or poorly soluble cross-linked polymer disintegrant. In turn, because claim 10 recites the composition of claim 3, it is not infringed by Ranbaxy's galantamine hydrobromide tablets either literally or under the doctrine of equivalents for the same reasons that claim 1 is not infringed either literally or under the doctrine of equivalents.

As such, for at least these reasons, claims 1-10 of the '863 patent are not infringed literally or under the doctrine of equivalents by the RLL tablet for which RLL is seeking approval to market in ANDA No. 77-588.

U.S. Patent No. 6,358,527 is Not Infringed

U.S. Patent No. 6,358,527 ("the '527 patent"), entitled "Fast-dissolving galantamine hydrobromide tablet ," issued on March 19, 2002 and is a continuation application of the '863 patent discussed above. This patent contains six claims, of which claims 1 and 6[2] are independent. The claims are as follows:

1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

2. The method of claim 1 wherein the disorder is dementia.

3. The method of claim 2 wherein the disorder is Alzheimer's dementia.

4. The method of claim 1 wherein the disorder is mania.

[2] Pursuant to 21 CFR §314.94(a)(12)(iv), an ANDA applicant is not required to certify to process claims. Nonetheless, our noninfringement position is provided to ensure that Janssen has an opportunity to review RLL's noninfringement position with respect to this process claim.

5. The method of claim 1 wherein the disorder is nicotine dependence.

6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

Claim 1 is directed to a method of treating a disorder selected from dementia, mania or nicotine dependence by administering a tablet that includes as an active ingredient a therapeutically effective amount of galantamine hydrobromide (1:1) and a pharmaceutically acceptable carrier. The carrier includes a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

Ranbaxy's galantamine hydrobromide tablet does not literally infringe claim 1 because Ranbaxy's tablets do not include an insoluble or poorly soluble cross-linked polymer disintegrant. As described in greater detail above, Ranbaxy's tablets include galantamine hydrobromide, MicroceLac® 100 (a spray-dried compound containing 75% alpha-lactose monohydrate and 25% microcrystalline cellulose), colloidal silicon dioxide, magnesium stearate, and pregelatinized starch. The tablets formed with these ingredients are coated with Opadry coatings. Because the claims of the '527 patent contain the same limitation as the '863 patent of "an insoluble or poorly soluble cross-linked polymer disintegrant", Ranbaxy's tablets do not infringe these claims either literally or under the doctrine of equivalents for the same reasons that claims 1-10 of the '863 patent are not infringed either literally or under the doctrine of equivalents.

Moreover, Ranbaxy's tablets do not infringe these claims under the doctrine of equivalents because of prosecution history estoppel in the application that resulted in the '527 patent. Specifically, the claim resulting in claim 1 of the '527 patent was rejected as being anticipated by U.S. Patent No. 4,663, 318 (Davis). In overcoming the rejection, the applicants

argued that the teaching of Davis "would not motivate one of ordinary skill in the art to make a pharmaceutical composition wherein the pharmaceutically acceptable carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant for use in treating dementia, mania, or nicotine dependence[.]" See Response dated March 7, 2001, page 3 (emphasis added). Because of the arguments in the Remarks, this claim was subsequently allowed in the next Office Action. Because the claim was allowed based on applicant argument over the use of an insoluble or poorly soluble cross-linked polymer disintegrant, the patentee cannot now attempt to expand the scope of the claims to cover polymer disintegrants that are not cross-linked, such as the pregelatinized starch used in Ranbaxy's tablets. For this additional reason, claim 1 and dependent claims 2-5 are not infringed under the doctrine of equivalents by Ranbaxy's galantamine hydrobromide tablets.

Independent claim 6 is directed a process of making a galantamine hydrobromide tablet. The process includes a step of blending galantamine hydrobromide with an insoluble or poorly soluble cross-linked polymer disintegrant. As such, for the same reasons that claim 1 is not literally infringed by the Ranbaxy tablet, claim 6 is not literally infringed.

Claim 6 also is not infringed under the doctrine of equivalents because of prosecution history estoppel. During prosecution of the application resulting in the '527 patent, the claim resulting in claim 6 was rejected for double patenting over claim 1 of the '863 patent and for lack of enablement for the use of any diluent or disintegrant. With respect to enablement, the Examiner asserted that the particular elements comprising the diluent and disintegrant were shown to effect the proper dissolution desired and therefore were considered critical.

In response to these rejections the applicants amended the claim to recite the disintegrant to be an insoluble or poorly soluble cross-linked polymer and the diluent to be a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). The applicant further argued in the Remarks that the claim was amended to "more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, Claim 16 has been amended to include the limitation that the disintegrant is an insoluble or poorly soluble

cross-linked polymer and the diluent comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)." The applicants also argued that the amendment to claim 16 (i.e., claim 6 of the '527 patent) fully enabled the claim. See Response dated August 22, 2001, pages 3-4.

This claim was subsequently allowed. Because the claim was allowed based on an amendment that the disintegrant be an insoluble or poorly soluble cross-linked polymer and remarks regarding the presence of an insoluble or poorly soluble cross-linked polymer disintegrant, the patentee cannot now attempt to expand the scope of the claims to cover polymer disintegrants that are not cross-linked, such as the pregelatinized starch used in Ranbaxy's tablets. For this additional reason, claim 6 is not infringed under the doctrine of equivalents by Ranbaxy's galantamine hydrobromide tablets.

As such, for at least these reasons, claims 1-6 of the '527 patent are not infringed literally or under the doctrine of equivalents by the RLL tablet for which RLL is seeking approval to market in ANDA No. 77-588.

OFFER OF CONFIDENTIAL ACCESS TO APPLICATION

Ranbaxy hereby extends an offer of confidential access to ANDA 77-588 that is in the custody of Ranbaxy. The conditions for confidential access are provided in the attached Confidential Disclosure Agreement ("CDA"). This offer and CDA are provided solely for the purpose of allowing Janssen Pharmaceutica and Johnson and Johnson to evaluate whether an action under 35 USC 271(e)(2)(A) should be brought for the filing of ANDA 77-588. This offer and the CDA contains restrictions as to persons entitled to access the ANDA, and on the use and disposition of any information accessed, as would apply if a protective order was entered for the purpose of protecting trade secrets and other confidential business information. Under section 505 of the Food, Drug and Cosmetic Act, a request for access to an application under an offer of confidential access is considered to be acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract.